

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: <i>Salonius, et al.</i>)	Int. Cl: A01K 61/00
Patent No: 7,302,913 B2)	U.S. Cl.: 119/215
Issued: December 4, 2007)	Atty Docket No. N079 1050.1
)	Conf. No. 7063

For: **VACCINE AGAINST SALMONID RICKETTSIAL SEPTICAEMIA BASED ON
ARTHROBACTER CELLS**

REPLY TO PARTIAL DENIAL OF REQUEST FOR CORRECTION

DECISIONS AND CERTIFICATES OF CORRECTION BRANCH

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

 This letter is submitted as a request for reconsideration of the partial denial of Applicants' Request for Correction filed April 23, 2008 and is responsive to the communication mailed June 3, 2008.

 In their previously filed Request for Correction, Applicants enclosed a copy of the International Search Report issued in parent Application No. PCT No. PCT/EP03/07605, issued December 30, 2003, a copy of Form PCT/DO/EO/903 (see acknowledgement of receipt of "Copy of references cited in ISR filed on 01/11/2005"), and a copy of the PTO-1449 and accompanying Information Disclosure Statement filed with the U.S. Patent Office on January 11, 2005.

 It should be noted that the Form PCT/DO/EO/903 attached with the previous submission acknowledges that the references in question were received and were in the record of the U.S. national application file. Applicants' PTO-1449 form, copy previously attached, was compliant with 37 CFR §1.98.

Applicants believe that the partial denial of their Request may have been related to the Examiner's having crossed through citations provided on Applicants' PTO-1449 form. However, as stated at the bottom of current PTO Form SB08A, the Examiner is only to take this action if the citation is *not in conformance* and the reference is not considered. (See bottom of SB08A: "Draw line through citation if not in conformance and not considered"). It is clear that, in the present situation, Applicants' citations *were in conformance*: further, copies were acknowledged as received by the Office. Accordingly, the Office was obligated to list the references on the face page of the patent because the Applicants had satisfied all requirements. The Examiner's notations were simply in error.

The Examiner's mistaken notations on a copy of Applicants' PTO-1449 are not a sufficient reason to refuse to list those references on the face page of the patent. As noted, Applicants had complied with all requirements for such listing. In view of the foregoing, Applicants respectfully request that the denial be reconsidered and that the Certificate of Correction issue as originally requested.

Respectfully submitted,



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Attorney for Assignee

Date: July 2, 2008

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INTERNATIONAL SEARCH REPORT

International Application No.
PCT/EP 03/07606

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K39/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

WPI Data, EMBASE, EPO-Internal, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 98 33884 A (GRIFFITHS STEVEN GARETH; SALONIUS KIRA (CA); AQUA HEALTH EUROP LTD) 6 August 1998 (1998-08-06)	7-14,21
A	the whole document	1-6, 15-20
Y	KUZYK M A ET AL: "An efficacious recombinant subunit vaccine against the salmonid rickettsial pathogen <i>Piscirickettsia salmonis</i> " VACCINE, BUTTERWORTH SCIENTIFIC. GUILDFORD, GB, vol. 19, no. 17-19, 21 March 2001 (2001-03-21), pages 2337-2344, XP004231046 ISSN: 0264-410X	7-14,21
A	page 2342, left-hand column, paragraph 2 -page 2343, left-hand column, paragraph 3	1-6, 15-20
-/-		

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *Z* document member of the same patent family

Date of the actual completion of the international search

3 December 2003

Date of mailing of the international search report

30/12/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5516 Patentplan 2
NL - 3200 HV Rijswijk
Tel. (+31-70) 340-6040, Tx. 31 651 spe nl,
Fax (+31-70) 340-6016

Authorized officer

Heiduschat, C

INTERNATIONAL SEARCH REPORT

International Publication No.

PCT/EP 03/07605

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 96 11707 A (OREGON STATE) 25 April 1996 (1996-04-25) the whole document	7-14, 21
A		1-6, 15-20
A	KUZYK M A ET AL: "ANTIGENIC CHARACTERIZATION OF THE SALMONID PATHOGEN PISCIRICKETTSIA SALMONIS" INFECTION AND IMMUNITY, AMERICAN SOCIETY FOR MICROBIOLOGY, WASHINGTON, US, vol. 64, no. 12, December 1996 (1996-12), pages 5205-5210, XP001029511 ISSN: 0019-9567 page 5208, left-hand column, paragraph 3 -page 5209, left-hand column, last paragraph	1-21
A	KOCH C ET AL: "16S RDNA STUDIES ON MEMBERS OF ARTHROBACTER AND MICROCOCCUS: AN AID FOR THEIR FUTURE TAXONOMIC RESTRUCTURING" FEMS MICROBIOLOGY LETTERS, AMSTERDAM, NL, vol. 123, no. 1/2, 1994, pages 167-171, XP002066096 ISSN: 0378-1097 page 168, right-hand column, paragraph 2 page 170, left-hand column, paragraph 2	1-21
A	GUDDING R ET AL: "Recent developments in fish vaccinology" VETERINARY IMMUNOLOGY AND IMMUNOPATHOLOGY, AMSTERDAM, NL, vol. 72, 1999, pages 203-212, XP002968601 ISSN: 0165-2427 page 207 -page 209	1-21
A	JONES S R M: "THE EFFECT OF MICROBIAL EXTRACTS ON THE SEVERITY OF EXPERIMENTAL PISCIRICKETTSIA SALMONIS INFECTION IN COHO SALMON, ONCORHYNCHUS KISUTCH" DEVELOPMENTS IN BIOLOGICAL STANDARDIZATION, KARGER, BASEL, CH, vol. 90, 1997, page 430 XP009016791 ISSN: 0301-5149 the whole document	1-21

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP 03/07605

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
Although claims 19 to 21 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:
because they relate to parts of the international Application that do not comply with the prescribed requirements to such an extent that no meaningful international Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCTASA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-6, 15 -20

Invention I: Use of live *Arthrobacter* cells for the preparation of a medicament for treatment or prevention of piscirickettsiosis in fish, vaccine composition or kit comprising live *Arthrobacter* in combination with a *P. salmonis* antigen and use thereof for protection against SRS and BKD.

2. Claims: 7, 8, 14 (completely), 9-13 (partially)

Invention II: Vaccine composition comprising live *Arthrobacter* cell in combination with an immunostimulant, e.g. cell material from killed *Arthrobacter* cells, or a further, non specified, immunogen

3. Claims: 9-13 (all partially), 21

Invention III: Vaccine composition comprising cell material from killed *Arthrobacter* cells as immunostimulant, use of killed *Arthrobacter* cell material as immunostimulant for fish.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No.

PCT/EP 03/07605

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9833884	A	05-08-1998	AU 5773998 A	25-08-1998
			EP 1012230 A1	28-06-2000
			WO 9833884 A1	06-08-1998
			US 6627203 B1	30-09-2003
WO 9611707	A	25-04-1996	US 5871751 A	16-02-1999
			AU 4000195 A	06-05-1996
			CA 2202499 A1	25-04-1996
			GB 2308300 A ,B	25-06-1997
			NO 971650 A	06-06-1997
			WO 9611707 A1	25-04-1996



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1459
 Alexandria, Virginia 22313-1459
 www.uspto.gov

U.S. APPLICATION NUMBER NO. 10/521,104	FIRST NAMED APPLICANT Kira Saloniis	ATTY. DOCKET NO. VA/H-32622A
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1095
 NOVARTIS
 CORPORATE INTELLECTUAL PROPERTY
 ONE HEALTH PLAZA 104/3
 EAST HANOVER, NJ 07936-1080

INTERNATIONAL APPLICATION NO. PCT/EP03/07605	
I.A. FILING DATE 07/14/2003	PRIORITY DATE 07/15/2002

CONFIRMATION NO. 7063
 371 ACCEPTANCE LETTER



Date Mailed: 02/28/2005

NOTICE OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C 371 AND 37 CFR 1.495

The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as a Designated / Elected Office (37 CFR 1.495), has determined that the above identified international application has met the requirements of 35 U.S.C. 371, and is ACCEPTED for national patentability examination in the United States Patent and Trademark Office.

The United States Application Number assigned to the application is shown above and the relevant dates are:

<u>02/14/2005</u>	<u>02/14/2005</u>
DATE OF RECEIPT OF 35 U.S.C. 371(c)(1), (c)(2) and (c)(4) REQUIREMENTS	DATE OF COMPLETION OF ALL 35 U.S.C. 371 REQUIREMENTS

A Filing Receipt (PTO-103X) will be issued for the present application in due course. THE DATE APPEARING ON THE FILING RECEIPT AS THE " FILING DATE" IS THE DATE ON WHICH THE LAST OF THE 35 U.S.C. 371 (c)(1), (c)(2) and (c)(4) REQUIREMENTS HAS BEEN RECEIVED IN THE OFFICE. THIS DATE IS SHOWN ABOVE. The filing date of the above identified application is the international filing date of the international application (Article 11(3) and 35 U.S.C. 363). Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

The following items have been received:

- Copy of the International Application filed on 01/11/2005
- Copy of the International Search Report filed on 01/11/2005
- Preliminary Amendments filed on 01/11/2005
- Information Disclosure Statements filed on 01/11/2005
- Oath or Declaration filed on 02/14/2005
- Copy of references cited in ISR filed on 01/11/2005 *
- U.S. Basic National Fees filed on 01/11/2005
- Priority Documents filed on 01/11/2005

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

PATRICIA A BOOKER

Telephone: (703) 308-9140 EXT 204

PART 3 - OFFICE COPY

FORM PCT/DO/EO/903 (371 Acceptance Notice)

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10	
EV 44378834805	January 11, 2005
Express Mail Label Number	Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF
SALONIUS ET AL.
INTERNATIONAL APPLICATION NO: PCT/EP03/07605
FILED: 14 JULY 2003
U.S. APPLICATION NO: Not Yet Assigned
35 USC §371 DATE:
FOR: VACCINE AGAINST SALMONID RICKETTSIAL SEPTICAEMIA BASED ON
ARTHROBACTER CELLS

MS: Amendment
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

This paper is being filed within three months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 of the international application. Therefore, no fees are required. If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-0134.

In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

The listed references were cited in the international stage search report. Since these references are of record in the instant PCT application PCT/EP03/07605, copies are not enclosed herewith.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,


David L. Marks
Attorney for Applicants
Reg. No. 37,881

Novartis
Corporate Intellectual Property
One Health Plaza, Building 104
East Hanover, NJ 07936-1080
(862) 778-7922
Date: January 11, 2005

FORM PTO-1449
(REV. 7-85)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

DT1 rec'd PCT/PTO 11 JAN 2005

Sheet 1 of 1

ATTY. DOCK
VAH-32622A
APPLICATION NO.
Not Yet Assigned
APPLICANT
SALONIUS ET AL.
FILING DATE

10/521104

Group

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						
	AL						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AM	WO 98 33884	8/6/98	WIPO			<input type="checkbox"/>	<input type="checkbox"/>
	AN	WO 96 11707	4/25/96	WIPO			<input type="checkbox"/>	<input type="checkbox"/>
	AO						<input type="checkbox"/>	<input type="checkbox"/>
	AP						<input type="checkbox"/>	<input type="checkbox"/>
	AQ						<input type="checkbox"/>	<input type="checkbox"/>

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

AR	Kuzyk et al., "An Efficacious Recombinant Subunit Vaccine Against the Salmonid Rickettsial Pathogen <i>Piscirickettsia Salmonis</i> ", Vaccine, Vol. 19, No. 17-19, pp. 2337-2342 (2001)
AS	Kuzyk et al., "Antigenic Characterization of the Salmonid Pathogen <i>Piscirickettsia salmonis</i> ", Infection and Immunity, Vol. 64, No. 12, pp. 5202-5210, (1996)
AT	Koch, et al., "16S RDNA Studies on Members of <i>Arthrobacter</i> and <i>Micrococcus</i> : An aid for their Future Taxonomic Restructuring", FEMS Microbiology Letters, Vol. 123, No. 1/2, pp 167-171, (1994)

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

FORM PTO-1449
(REV. 7-85)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

DT1 ac'd PCT/PTO 11 JAN 2005

Sheet 2 of 2

ATTY. DOCK
VAH-32622A
APPLICATION NO.
Not Yet Assigned
APPLICANT
SALONIUS ET AL.
FILING DATE

10/521 104

Group

EXAMINER
INITIAL

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

	DA	Gudding et al., "Recent Developments in Fish Vaccinology", Veterinary Immunology and Immunopathology, Vol. 72, pp 203-212, (1999)
	DB	Jones, "The Effect of Microbial Extracts on the Severity of Experimental <i>Piscirickettsia Salmonis</i> Infection in COHO Salmon, <i>Oncorhynchus Kisutch</i> ", Developments in Biological Standardization, Vol. 90, page 430, (1997)
	DC	
	DD	
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	DH	
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	DK	
	DL	
	DM	
	DN	

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.